DETAILED ACTION

This action is in response to the applicant's amendment received 04 November 2011. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 2, 4, 8, 16, 18, 20, and 22-47 are cancelled.

Response to Arguments

Applicant's arguments filed 04 November 2011 have been fully considered but they are not persuasive. The applicant argues that one of ordinary skill in the art would have no reason to utilize a biodegradable metallic or ceramic material as Hossainy's inner core material. However, Bolz teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for example, see column 3, lines 11-35) with the bioresorbability of polymer-based stents (for example, see column 2, lines 6-16). Therefore, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz in order to provide the inner core with the mechanical advantages described above. The applicant further argues that since Hossainy teaches a polymeric coating, Hossainy teaches away from the use of a degradable metallic inner core. However, Hossainy does not disclose or suggest a degradable metallic material could not be utilized as the inner core material. Furthermore, Hossainy discloses the inner core may comprise metallic, nonmetallic, and absorbable materials. Therefore, it is the examiner's

position that Hossainy does not teach away from utilizing a degradable metallic material as taught by Bolz.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-7, 9-15, 17, 19, 21, and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252) and Bolz (U.S. Patent No. 6,287,332 B1).

Hossainy discloses an implantable medical device (stent; see entire document) comprising a biodegradable inner core (for example, see column 3, lines 10-21), thus becoming decreasingly rigid upon contact with bodily fluid, a biodegradable covering material completely covering the inner core material as a coating thereon (for example, see column 3, lines 55-58 and column 4, lines 1-14) and does not contain a therapeutic agent therein (an alternate embodiment may contain agents if desired), and one or

more additional biodegradable coating layers that do not contain therapeutic agent (for example, see column 7, lines 11-15), wherein the entire medical device is substantially biodegradable by the body (i.e., both the cover and inner core may be biodegradable). The covering material may be formed of a hydrophobic surface erodable polymer (for example, polyamide, polyorthoester, or polyanhydride; for example, see column see 5, lines 6-12), thus is capable of controlling the rate at which the inner core material becomes flexible upon contact with bodily fluids. Hossainy discloses the inner core may be metallic, an absorbable plastic, or any other suitable material which can provide the necessary mechanical requirements of a stent, but fails to disclose the biodegradable inner core material is specifically selected from biodegradable metallic or ceramic materials.

Bolz discloses an implantable medical device, such as a bioresorbable stent (see entire document). Bolz teaches constructing the bioresorbable stent of degradable metallic materials. Bolz further teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for example, see column 3, lines 11-35) with the bioresorbability of polymer-based stents (for example, see column 2, lines 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz. Doing so would provide the mechanical advantages described above.

With further respect to claims 7, 10, and 50, such materials are well known in the art and thus it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the inner core and covering from the materials recited, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With further respect to claims 11-13, Hossainy discloses the inner core material may comprise a cylindrical stent with perforated passages, a cylindrical structure formed of helical wound or serpentine wire structures, or a rolled tubular structure that is woven, wrapped, drilled, etched, or cut to form passages. Hossainy fails to disclose whether the filaments utilized are monofilaments or multifilaments. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the inner core comprising either monofilaments or multifilaments, since such configurations are well known in the art and the applicant has failed to disclose that such configurations provide an advantage, are used for a particular purpose, or solve a stated problem. It appears the invention would perform equally well with any configuration, including configurations disclosed by Hossainy.

Claim 15 is being treated as a product by process limitation, in that “the tubular structure is micromachined or laser-cut” refers to the process of forming the tubular structure and not to the final product created. As set forth in MPEP 2113, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not

depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a stent as described above wherein the tubular body is formed by micromachining or laser-cutting is directed to the method of making the stent and not to the final product made. It appears that Hossainy's modified product would be the same as that claimed, especially since both applicant's product and the prior art product have the same final structure of a biodegradable inner tubular structure and a biodegradable covering material.

With further respect to claims 19 and 21,Hossainy's modified stent is capable of being used as claimed if one so desires.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-90629062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Primary Examiner, Art Unit 3773
December 6, 2011